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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA

BNSF RAILWAY COMPANY, on behalf of THE UNITED STATES OF AMERICA Plaintiff vs. THE CENTER FOR ASBESTOS RELATED DISEASE, INC. Defendant.	Civil Action No.: CV-19-40-M-DLC **FILED UNDER SEAL** pursuant to 31 U.S.C. § 3729 et seq. **SECOND AMENDED COMPLAINT AND JURY DEMAND**

FALSE CLAIMS ACT "QUI TAM" COMPLAINT

The United States of America, by and through qui tam Relator, BNSF Railway Company ("BNSF"), brings this action under 31 U.S.C. §§ 3729-33 (The "False Claims Act") to recover from The Center for Asbestos Related Disease, Inc.

("CARD") for all damages, penalties, and other remedies available under the False Claims Act on behalf of the United States and itself, and alleges based upon information, knowledge and belief the following:

PARTIES

1. Relator, BNSF is a Delaware corporation with a principal place of business in Fort Worth, Texas. BNSF has direct and independent knowledge of all publicly disclosed and other information upon which the allegations herein are based. BNSF is the original source of the false claims allegations contained in this Complaint. Before filing this Complaint, BNSF made a disclosure of all material evidence and information in its possession to the government as required by 31 U.S.C. § 3730(b)(2).

2. CARD is a Montana non-profit corporation. Its registered agent for service of process is Tracy McNew, 214 East 3rd Street, Libby, Montana 59923.

JURISDICTION AND VENUE

3. This Court maintains subject matter jurisdiction over this action pursuant to 31 U.S.C. §3732(a) (False Claims Act) and 28 U.S.C. § 1331 (Federal Question).

4. Venue is proper in this Court under 28 U.S.C. § 1391(b) and (c), and 31 U.S.C. § 3732(a) because CARD can be found and/or resides in the District of

Montana, and CARD transacts business within this district and the facts forming the basis of this Complaint occurred within this district.

5. The facts and circumstances of Defendant's violations of the False Claims Act have not been publicly disclosed in a criminal, civil or administrative hearing; nor in any legislative, administrative, or inspector general report, hearing, audit or investigation or in the news media.

6. Relator discovered the information contained herein in 2018 and 2019 through its involvement in consolidated asbestos litigation in the State of Montana in the Asbestos Claims Court pertaining to individuals claiming asbestos exposure while in Libby, Montana.

SCREENING FRAUD IN TORT LITIGATION

7. Much has been written about screening fraud perpetrated on courts and others through misdiagnoses of lung diseases. *See In re Silica Products Liability Litigation*, 398 F.Supp.2d 563 (S.D. Tex. 2005); ABA Commn. on Asbestos Litig., *ABA Report to the House of Delegates, Recommendation and Resolution*, at 8 (2003).

8. For example, in a 2004 study by researchers at Johns Hopkins University, a panel of B Readers (physicians certified in the reading of chest x-rays) were asked to re-read 492 x-rays that were obtained from plaintiffs' lawyers. The original readers, who had been hired by screening companies, claimed to find

evidence of possible asbestos-related lung damage in 95.9% of the x-rays. In stark contrast, the B Readers of the uninterested panel, who were unaware of the original findings, only found 4.5% of the x-rays showed any signs of possible injury attributable to asbestos. Joseph N. Gitlin, et al., *Comparison of "B" Readers' Interpretations of Chest Radiographs for Asbestos Related Changes*, 11 Acad. Radiology 843 (2004).

9. A significant diagnostic differential rate is the hallmark of screening fraud cases nationally and was the subject of Congressional inquiry after the *In Re Silica* case. *See* H.R. Jud. Comm., *How Fraud and Abuse in the Asbestos Compensation System Affects Victims, Jobs, the Economy and the Legal System,* 112th Congress (September 9, 2011).

FACTUAL BACKGROUND

10. From the late 1920s to 1990, W.R. Grace & Co. ("Grace") mined and milled vermiculite ore in and around Libby, Montana. For many years, Grace's Libby mine was the world's largest producer of vermiculite, a non-toxic mineral useful for a variety of applications, including attic insulation, fireproofing products, masonry fill, fertilizer, and potting soil. The raw ore extracted from Zonolite Mountain contained vermiculite, asbestos and other minerals. The product left after processing and milling was ostensibly a refined vermiculite concentrate, a product Grace represented and marketed as safe. Residents of Libby, Montana have brought

claims for years against W.R. Grace. Since Grace's bankruptcy, thousands of plaintiffs have turned their derivative claims towards the State of Montana, International Paper, BNSF and others for Asbestos Related Disease allegedly caused by second-hand exposure to Grace's vermiculite mining and processing activities.

11. Defendant, CARD, was born, and evolved, in response to raised awareness of asbestos exposure in the Libby, Montana area that surfaced in 1999. In 2000, CARD was established as a department of St. John's Lutheran Hospital to provide screening, diagnosis, treatment and monitoring for those exposed to Libby amphibole asbestos. In April 2003, CARD separated from St. John's Lutheran Hospital and became a stand-alone organization.

12. Since its inception, CARD and its medical providers have screened thousands of patients for the presence of Asbestos Related Disease ("ARD").

13. CARD states in its Patient Education literature that it, "provides comprehensive asbestos health screening that is important for all people with a history of asbestos exposure in Lincoln county."

14. CARD further states that it provides: "Specialty Libby Amphibole Pulmonary Health Care: Disease management and treatment services are available at the CARD Clinic in Libby, Montana. This specialty care is valuable for the approximately 7,000 patients followed by CARD and the new patients who present

daily for screening assessment and information regarding the possible effects of their asbestos exposure."

15. Well over 1,000 of CARD's patients have been involved in litigation in Montana Courts based on claims that they have been diagnosed with an asbestos related disease.

Federal Grants and Federal Legislation that Support CARD

16. CARD is primarily funded by the receipt of federal grant monies administered by the American Toxic Substances Disease Registry ("ATSDR") and the Centers for Disease Control ("CDC").

17. Since 2011, CARD's primary screening grant awards have totaled approximately $2.4M annually: "PPHF-14-Libby Montana's Public Health Emergency: Asbestos Health Screening" (Grant # U61TS000179 from 2011-2015; Grant # NU61TS000251 from 2016-2018 and Grant # NU61TS000295 in 2019).

18. From 2011 until the present, CARD has been awarded over $20M dollars in federal funds through the primary screening grant alone.

19. The first four-year grant period ran from July 1, 2011, to June 2015.

20. The federal government extended the grant by another four years on August 21, 2015.

21. The term of this extension ran from September 1, 2015, to August 31, 2019 at a rate of between $2.3M and $2,499,995 per year.

22. The federal government extended CARD's grant by another four years on July 19, 2019.

23. These grant funds pay for CARD staff salaries, education and outreach related to Asbestos Related Disease ("ARD") and for screening services and radiographic studies such as chest x-rays and Computed Tomography (CT scans).

24. As a condition of these grant monies, CARD has reporting requirements related to the scope of CARD's screening program and the expenditure of grant funds as set forth by federal law. *See* 45 C.F.R. 74 et seq. (2011).

25. In 2011, the Medicare Pilot Program for Asbestos Related Disease ("Pilot Program") was created which provides comprehensive care for individuals diagnosed with a qualified asbestos related condition, including services not normally covered under Medicare, for residents in Lincoln and Flathead Counties. 42 U.S.C. § 1881A(a)(1) and (b).

26. Subsequent to its creation in 2011, individuals enrolled in the Pilot Program were entitled to Medicare coverage benefits for complete healthcare, not just asbestos related healthcare.

27. These Medicare coverage provisions appear in a special section of the Affordable Care Act specifically focused on the diagnosis of asbestos related disease. This provision is titled "Medicare coverage for individuals exposed to environmental health hazards." 111 Pub. L. No. 111-148, § 10323, 124 Stat. 119,

954 (2010) [42 U.S.C. § 1395rr-1]; amending Title XVIII of the Social Security Act (42 U.S.C. § 1395 et seq.) by inserting 42 U.S.C. § 1881A.

Requirements for Coverage of Asbestos Related Disease under Medicare

28. A qualifying condition for Medicare coverage and other benefits is that CARD patients must be diagnosed with a host of qualifying impairments related to asbestos exposure.

29. Two of the primary qualifying impairments are "Asbestosis" or "Pleural thickening/Pleural plaques." 42 U.S.C. § 1881A(e)(2)(B)(i).

30. The diagnosis for "Asbestosis" must be based on the "Interpretation by a B reader qualified physician of a plain chest x-ray or interpretation of computed tomographic ("CT") radiograph of the chest by a qualified physician." 42 U.S.C. § 1881A(e)(2)(B)(i)(I).

31. The diagnosis for "Pleural thickening/Pleural Plaques" must be based on the same criteria of "Interpretation by a B reader qualified physician of a plain chest x-ray or interpretation of computed tomographic radiograph of the chest by a qualified physician." *Id.*

32. A "qualified physician" under these provisions of the Affordable Care Act is one who performs radiographic scans and interpretations in conformity with the accepted medical standards of care and the American Thoracic Society (ATS) guidelines.

33. A "qualified physician" practicing as a radiologist who interprets chest x-rays and CT scans must also adhere to the standards of care for radiologists published by the American College of Radiology (ACR), the National Institute for Occupational Safety and Health (NIOSH) guidelines and the International Labour Organization (ILO) guidelines.

34. Under Montana law and the medical standards of care in Montana, in order to be deemed a "qualified physician," a physician who practices specialized medicine in a field outside his or her field of specialty must conform to that specialist's standards of care.

35. Both "Asbestosis" and "Pleural thickening/Pleural plaques" share a Diagnosis Code of "5010" as recorded by CARD.

36. This information is recorded on an "Environmental Health Hazards Checklist" Form ("EHH"), signed and dated by CARD employees and submitted by CARD to the federal government to obtain Medicare coverage and other benefits for individual patients on the basis of exposure to an environmental health hazard (namely asbestos) pursuant to the Affordable Care Act at 42 U.S.C. §1881A.

37. The minimum evidence required for a finding of "Asbestosis" and "Pleural thickening/Pleural plaques" is not only expressly set forth on the EHH form, it is also set forth by federal law under the Affordable Care Act. 42 U.S.C. § 1881A(e)(2)(B)(i)(I).

38. CARD has submitted thousands of these EHH forms to the federal government, certifying thousands of patients for Medicare coverage and other benefits as having one or both "Asbestosis" and "Pleural thickening/Pleural plaques."

39. In hundreds of CARD cases, this diagnosis has been based on CARD's interpretation of a chest CT scan or x-ray alone, ***without*** a supporting radiographic interpretation from a "B Reader," Radiologist or Pulmonologist.

A Novel Lung Condition that No One Else can Detect but CARD

40. Dr. Brad Black is CARD's Chief Executive Officer and Medical Director. Dr. Black has been with CARD since the clinic's inception.

41. Dr. Black is a pediatrician by specialty.

42. Dr. Black is not a pulmonologist.

43. Dr. Black is not a radiologist.

44. Dr. Black is not a Certified B Reader.

45. CARD does not currently regularly employ any of these specialized practitioners at its facility in Libby, Montana.

46. No medical care providers at CARD are certified, licensed or formally trained as radiologists or formally trained or credentialed in diagnostic radiographic interpretation.

47. No staff or employees at CARD are certified or formally trained radiology technicians.

48. Furthermore, CARD's facility has no x-ray or CT scanning equipment on site.

49. Dr. Black, along with others associated with CARD, have devised a novel diagnosis for asbestos related disease called "Lamellar Pleural Thickening."

50. This condition is not commonly recognized by the medical community and is virtually unheard of – and unused - by anyone other than CARD providers or "litigation doctors" associated with Libby asbestos.

51. Dr. Black and CARD providers claim that this condition is unique to Libby Asbestos exposure and is not readily apparent to the "untrained" eye on radiographic studies such as x-rays and computed tomography ("CT scans").

52. Dr. Black claims that signs of asbestos related disease caused by the Libby amphibole are nonspecific and difficult to detect.

53. Dr. Black has asserted that often he alone can perceive signs of asbestos related disease on CT scan caused by the Libby amphibole, claiming: "What the mind does not know, the eye does not see."

54. "Lamellar Pleural Thickening" has virtually no identifiable diagnostic criteria according to CARD, only that it appears very much like a thin layer of subpleural fat in the membrane that lines the lungs.

55. "Lamellar Pleural Thickening" is not a diagnosis listed in the International Statistical Classification of Diseases and Related Health Problems ("ICD-10"), the ICD-10 Clinical Modification ("ICD-10-CM"), regularly used by the World Health Organization or Department of Public Health and Human Services, or validated by the New England Journal of Medicine or any other peer-reviewed studies.

56. CARD routinely uses the diagnosis of "Lamellar Pleural Thickening" to describe changes Dr. Black claims he observes on CARD patients' CT scans.

57. This condition - seen by none but Dr. Black and other CARD associated providers - then frequently becomes the basis for CARD's certification on EHH forms that a patient has an asbestos related disease.

Diagnostic Dissension between CARD and Outside Radiologists

58. There is a significant gap in diagnosis rates between CARD and all other outside radiologists who read and interpret CARD patient CT scans for signs of asbestos related disease.

59. The phenomenon of "Lamellar Pleural Thickening" explains this diagnosis gap in part.

60. CARD maintains a high diagnosis rate among its patients for asbestos related disease.

61. CARD reads approximately 64% of its patients' CT scans as positive for asbestos related disease based on data from CARD's own records.

62. CARD's diagnostic rate has remained relatively consistent year to year and is significantly higher compared to all radiologists who find pulmonary signs that *could* be consistent with asbestos related disease in only about 35% of the same patients.

CARD's Disregard of Outside Radiologist's Interpretations

63. As part of its federal grant, CARD receives – and serves as a pass through - for millions of dollars in federal funds earmarked for referrals for CARD patients to radiologists who perform and interpret x-rays and CT scans.

64. One provision of the grant award language states that *all radiologic exams will be sent for outside reads to a panel of expert B-readers and radiologists that will be established by CARD and ATSDR.*

65. The fundamental purpose of these federal grant provisions requiring the use of a panel of multiple, independent, outside radiologists is to ensure the accuracy of each diagnosis of asbestos related disease.

66. This fundamental purpose was enshrined in the standard screening protocols developed as part of CARD's first screening grants. *See* CARD's "Asbestos Screening and Diagnostic Methodology" (September 21, 2009).

67. These screening protocols dictated that CT scans and chest x-rays should be sent to *"outside expert"* radiologists who were *"neutral"* and could substantiate structural evidence consistent with asbestos induced abnormality.

68. These protocols clarified procedures for resolving diagnostic dissension, stating that *"if the diagnosing physician's opinion differs, then the opportunity for expert medical panel review will be available for final determination of medical eligibility."*

69. There are three primary categories of radiologists who take x-rays and CT scans of CARD patients:

70. A "local" radiologist - who usually takes a CT scan of CARD patients at a clinic in or near Libby, Montana and interprets that scan within days of the patient's initial visit at CARD;

71. An "outside" radiologist - a NIOSH certified thoracic radiologist who reviews and interprets a mailed copy of the initial CT scan taken by the local radiologist months after the initial CT scan was taken; and

72. A "peer review" radiologist - a NIOSH certified thoracic radiologist who sits on a panel of similarly qualified radiologists who also reviews and interprets a mailed copy of the initial CT scan taken by the local radiologist.

73. CARD routinely diagnoses patients with ARD ***before*** any of these scans are interpreted by qualified "outside" radiologists.

74. Even in cases in which each of these qualified radiologists' interpretive reports unanimously show no findings of asbestos related disease, CARD still stands by its positive diagnosis of ARD.

75. These misdiagnosed patients are then included as "diseased" patients in CARD's reports to the federal government.

76. By doing so, CARD inflates the clinic's overall number of "ARD" patients.

CARD's Master Data Set

77. The fact that CARD routinely diagnoses patients without a supporting outside radiologist's CT interpretation is well known to CARD and its staff.

78. Internal data generated by clinic staff as part of the federal grant requirement shows that CARD is aware of the results of every outside CT and chest x-ray interpretation received by CARD.

79. Accordingly, CARD is also aware of the stark diagnostic differential between Dr. Black and all outside CT reading radiologists.

80. CARD maintains a "Master Data Set" that records the total number of patients that have received screening services through the CARD facility.

81. These internal records show the extent to which CARD routinely disregards the findings of local radiologists, outside radiologists, B-readers, and Peer

Review CT readers who frequently unanimously disagree with CARD's diagnosis of disease.

82. This Master Data Set also disproves misstatements CARD has made to the federal government.

83. In its report to the CDC after the first four years of the grant, CARD stated that CARD's CT diagnosis rate for asbestos related disease was "47% versus a 41% diagnosis rate by outside readers."

84. However, CARD's own Master Data Set shows that CARD's diagnosis rate is much higher than outside radiologists.

85. Based on an analysis of this data, CARD obtained over 4,000 CT scans for its patients as of August 1, 2018.

86. Of that number, CARD read approximately 64% of the CT scans as showing signs of an Asbestos Related Disease.

87. By contrast, CARD's internal data shows that "Outside" CT readers found lung abnormalities in only approximately 35% of CARD patients' scans.

88. The fact that an "abnormality" exists does not mean that the outside CT reader has diagnosed the patient with ARD. This merely signifies that the patient's CT showed signs that might be "consistent with" ARD.

89. These abnormalities could likewise be "consistent with" other conditions, such as tobacco use, rib fractures, prior thoracic surgery, radiation therapy or the use of certain medications.

90. A close analysis of other data in CARD's records shows that CARD's actual diagnostic rate may be even higher.

91. For example, of the 518 CT scans completed in Year 1 of the first federal grant period, CARD diagnosed 375 patients with asbestos related disease according to CARD's Final Report for Year 1.

92. This translates to a positive diagnosis rate of 72% for Asbestos Related Disease for those patients.

93. All 375 of those patients were reported as eligible for Medicare.

94. Other figures in CARD's Master Data set show that CARD's Medicare eligibility rate consistently surpasses the rate of patients who show objective signs of abnormality on either CT or chest x-ray.

95. Based on CARD's Master Data Set, less than half of the patients diagnosed with asbestos related disease by CARD based on a CT scan showed signs of disease according to "Outside CT" readers - a fact known to CARD providers.

96. As a result, CARD has diagnosed close to one thousand patients with asbestos related disease and designated them as Medicare eligible when those

patients showed ***no*** signs of any abnormalities on CT scan according to qualified radiologists.

CARD's "Peer Review Panel" of Thoracic Radiologists

97. As part of its federal grant requirements, CARD submits CT scans to the aforementioned "Peer Review" panel of radiologists.

98. Since 2010, CARD has submitted over two-hundred CT scans to its peer review panel that Dr. Black has read as positive for signs of asbestos related disease.

99. But even CARD's hand-picked panel of "expert CT readers" unanimously disagreed with Dr. Black's diagnosis of ARD much of the time – more often than the panel agreed with his positive diagnosis.

100. Based on CARD's internal data, even in the dozens of cases in which ***all*** outside peer reviewers unanimously found no signs of asbestos related disease, CARD still submitted those patients for Medicare coverage and other federal benefits.

101. CARD has not provided full disclosure regarding these discrepancies to its patients or the federal government. Accordingly, hundreds of CARD patients are living with no knowledge that they have apparently been misdiagnosed with a lethal disease.

102.

Conditions for Receipt of Federal Grant Awards

103. Federal grant awards to organizations and individuals are predicated on true and accurate grant applications and other statements to the federal government.

104. Receipt of grant awards also involves certain continuing conditions, responsibilities and obligations: "These responsibilities include accountability both for the appropriate use of funds awarded and the performance of the grant supported project or activities as specified in the approved application." *See* U.S. Dept. of Health and Human Services, *HHS Grants Policy Statement* (January 1, 2007); *https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf*

105. One of the conditions involved in obtaining federal grant funds is to share true, accurate and complete information with the granting agency. Penalties, including revocation of the grant, can be imposed if information contained in or submitted as part of a grant application or other required reports is found to be false, fictitious or fraudulent. *Id.* at p. I-7 et seq.; *See* 45 C.F.R. pt. 74 (2011); *See also* 45 C.F.R. § 79.3 (2011).

106. Another condition for keeping and renewing these government grants, is that CARD must certify that all federal monies used are consistent with the original grant purpose. 45 C.F.R. § 74.20 et seq. (2011).

107. This certification exists in the form of an Annual Progress Report (APR), a Final Progress Report and a Federal Financial report.

108. These reports are authored and forwarded by CARD to the Grants Management Office at the Centers for Disease Control. All expenditures of grant monies must be consistent with the purpose of the grant itself and specifically earmarked and recorded as required by the terms of the grant and federal reporting requirements.

109. From on or about June 1, 2011, continuing until July 19, 2019, in CARD's applications and reports related to grant award numbers U61TS000179; U61TS000251; NU61TS000251 and NU61TS000295, CARD made material representations to the federal government about screening procedures, diagnostic rates, the medical necessity of the expenditure of federal funds and other aspects of CARD's screening program that were false, misleading and showed deliberate ignorance of, or reckless disregard for the truth, to wit:

a. In CARD's grant applications, year-end final grant reports, quarterly reports and elsewhere, CARD represented to the federal government that all CT diagnoses of ARD are supported by an "Outside CT read."

b. In CARD's grant applications, year-end final grant reports, quarterly reports and elsewhere, CARD represented to the federal government

that CARD patients would be eligible for Medicare through the Environmental Health Hazard designation in one of three ways:

> *(1) They are eligible through a positive B read of a chest x-ray.*
>
> *(2) They are eligible through a positive CT read by an outside radiologist.*
>
> *(3) They are eligible because they have a documented diagnosis of an asbestos related cancer.*

c. In CARD's grant applications, year-end final grant reports, quarterly reports and elsewhere, CARD represented that each CARD diagnosis was based on an x-ray interpretation by a B reader, or an Outside CT read that shows objective signs in the lungs of structural abnormality.

d. In CARD's grant applications, year-end final grant reports, quarterly reports and elsewhere, CARD represented that ***"CARD's diagnosis rate is 47% versus a 41% diagnosis rate by outside CT readers…"*** CARD's grant application and reporting paperwork also states: ***"it is noteworthy that over the course of the prior grant and this grant to date, 40% of outside CT scan reads have identified abnormalities and most abnormalities were pleural rather than parenchymal."***

e. In CARD's grant applications, year-end final grant reports, quarterly reports and elsewhere, CARD represented that it submitted 24 patients' CT scans for outside Peer Review. CARD stated that 19 of those 24

patients showed signs of ARD: "Of the 24 CT's read by three different readers, 19 were read as positive. Of the 19 positives, 11 were read positive for asbestos related pleural disease and 8 were read positive for asbestos related parenchymal disease." In truth and fact, a review of CARD's underlying data shows that 12 of the 24 peer-reviewed patients had absolutely ***no*** positive findings of ARD as determined by the unanimous conclusion of all CT readers for either pleural or parenchymal ARD. Of the remaining 12 patients, findings by peer reviewers indicated equivocal results in most cases and only one peer-reviewed patient showed a unanimous finding of signs consistent with ARD by all outside CT readers. These types of half-truths and misrepresentations are a hallmark of CARD's statements in reports to the federal government.

f. In CARD's grant applications, year-end final grant reports, quarterly reports and elsewhere, CARD represented that it follows the standards of care promulgated by the American Thoracic Society ("ATS"), which requires evidence of structural change visible on radiographic study, evidence of plausible causation and the exclusion of alternative diagnoses. In truth and fact, as admitted by Dr. Black, CARD's diagnoses are "weighted" with focus primarily placed on exposure

history alone, without regard for a lack of objective evidence of structural change or exclusion of alternative diagnoses.

g. In CARD's grant applications, year-end final grant reports, quarterly reports and elsewhere, CARD stated that it "over reads" CT scans of outside radiologists, when in truth and fact CARD frequently diagnoses ARD and shares that diagnosis with patients *before* a local radiologist has forwarded a CT interpretation to CARD, and prior to "Outside" CT reads ever being returned to the facility.

h. In CARD's grant applications, year-end final grant reports, quarterly reports and elsewhere, CARD stated that it uses an outside CT Peer Review Program to ensure reliable diagnoses, when in truth and fact, CARD routinely disregards "Peer Review" CT interpretations.

i. In CARD's grant applications, year-end final grant reports, quarterly reports and elsewhere, CARD states that CARD clinicians follow the standards, procedures and protocols of NIOSH quality standards for detection of pneumoconiosis, ATS standards and ILO guidelines, when in truth and fact, CARD routinely ignores key components of these standards and guidelines, to wit: CARD deviates from these standards by failing to read CT scans and B reads "blindly." That is, CARD is aware of patient exposure history in each patient at the time Dr. Black

and other CARD clinicians perform their own CT interpretations. CARD fails to consider outside CT reader interpretations that state no finding of abnormalities, even though ILO and ATS standards require further evaluation in the face of variability and discrepancy among CT reads. CARD's patient records show that CARD also routinely fails to consider alternate diagnoses of abnormal findings on CT's and chest x-rays, even though this is explicitly required by ATS guidelines.

j. In CARD's grant applications, year-end final grant reports, quarterly reports and elsewhere, CARD states that its screening program effectively uses outside radiologists' scans and interpretations and that federal monies spent for such services are medically necessary. In truth and fact, as CARD patient medical records, Dr. Black's deposition testimony and CARD's Master Data Set show, these radiologists' interpretations are routinely disregarded by CARD and have no diagnostic value.

110. CARD's foregoing statements were false, based on misrepresentations, half-truths, deliberate ignorance of and reckless disregard of the truth.

111. CARD's false statements concealed facts related to CARD's screening practices.

112. CARD's false statements also exaggerated the number of patients suffering from asbestos related disease due to the Libby Amphibole, thus justifying continued funding of CARD's federal grants. An exaggerated number of sick patients might tend to increase the likelihood that the federal government would continue to issue higher-than-warranted amounts of federal grant funds to study, screen and treat an inflated number of ARD diagnosed CARD patients.

113. CARD knowingly published these false and misleading statements in its grant applications and periodic reports to the CDC and ATSDR in order to increase its chances of winning and maintaining CARD's federal grant awards in amounts totaling approximately $2.4M annually.

114. Each statement referenced herein, made or forwarded by CARD in support of payment of federal grant funds constitutes a false claim for payment by the federal government pursuant to 31 U.S.C. § 3729 as set forth below.

"Medical Necessity" as a Requirement for Government Funds

115. Pursuant to policies, procedures and requirements governing federal grants, all expenditures of grant funds for medical treatment and services must be "medically necessary." *See* 45 C.F.R. 74 et seq. (2011); *See also* U.S. Dept. of Health and Human Services, *HHS Grants Policy Statement* (January 1, 2007); *https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf*

116. These same federal provisions also require that grant recipients must take steps to avoid fraud, waste or abuse of government funds and must report any knowledge of fraud, waste or abuse to the federal government. *Id.*; 45 C.F.R. § 74.51 et seq. (2011); 45 C.F.R. pt. 74, app. E (2011).

117. As the recipient of a federal grant award, CARD was placed on a reimbursement plan called the manual payment method. Under this plan, the CDC Grants Management Officer (GMO) or Grants Management Specialist (GMS) monitors and controls all payment advances for the award. In order to receive these funds, the grantee must submit a Standard Form (SF) 270 Request for Advance or Reimbursement, a monthly disbursement plan that reflects costs associated with this award, and any additional documentation to support the request.

118. All documentation submitted to the government related to the use of funds must be signed and dated by a CARD representative.

119. CARD's funding requests are forwarded to the Centers for Disease Control and Prevention in Atlanta, Georgia.

120. By accepting the award, and drawing down funds, the recipient (CARD) acknowledges acceptance of the terms and conditions of the award and is obligated to perform in accordance with the requirements of the award.

False Claims for Medically Unnecessary Screening Services

121. CARD submits Screening Invoices to the CDC Procurement and Grants Office in Atlanta, Georgia for payments from CARD's federal grant funds (1U61TS000179-01) for "expert imaging reads" and other services related to CT scans and chest x-rays.

122. Based on these invoices, the federal government awards CARD grant money totaling approximately $500,000 annually to pay for radiographic scans and interpretations performed by qualified physician radiologists who work at outside screening facilities.

123. By routinely diagnosing patients with ARD *before* an "outside" CT radiologist's interpretation is completed or returned, CARD effectively disregards all radiographic interpretations performed by qualified physicians and renders all outside CT interpretations moot and medically unnecessary.

124. "Outside" CT interpretations do not even arrive at CARD until months after patients have already been diagnosed.

125. CARD does not consider B-reader chest x-rays for any diagnostic purpose, nor are B-reads included in patients' medical charts.

126. CARD consistently fails to meaningfully inform patients at the time of their diagnosis that the qualified radiologist who interpreted their CT scan determined that the patient showed no signs of asbestos related disease.

127. Once CARD diagnoses a patient with asbestos related disease, CARD does not change its diagnosis in the face of further radiographic interpretations from any "Outside" radiologists or CARD's Peer-Review panel, even when all interpretations unanimously confirm the absence of disease.

128. Over the life of CARD's federal screening grant, CARD has knowingly billed the government millions of taxpayer dollars for thousands of medically unnecessary radiographic studies and interpretations that CARD routinely disregards. Patient B-reads showing no signs of ARD are not even retained as part of patient medical records at CARD. CARD's refusal to consider these radiographic interpretations prior to diagnosis renders them meaningless for diagnostic purposes.

129. Billing the federal government for medically unnecessary services constitutes fraud, waste and abuse, in violation of federal grant requirements. *See* 45 C.F.R. pt. 74 et seq. (2011).

130. Pursuant to rules governing federal grants (referenced herein) CARD itself has an obligation to prevent and report fraud, waste and abuse related to its own use of any federal grant funds. 45 C.F.R. pt. 74 et seq. (2011).

131. CARD has not fully informed the federal government – or CARD patients - of these routine practices related to its screening program.

132. Each statement referenced herein, made or forwarded by CARD in support of payment of federal grant funds for unnecessary screening services

constitutes a false claim for payment by the federal government pursuant to 31 U.S.C. § 3729 as set forth below.

False Claims for Sub-Award Funds from Mount Sinai School of Medicine

133. CARD has also received "sub award" grant funding from the Mount Sinai School of Medicine in New York.

134. This sub award grant exceeded $300,000 in 2013. (Prime Award No. 5 R01 TS000099-04); (Sub Award No. 0254-5674-4609).

135. Like the other federal grant awards CARD receives, by drawing down or otherwise obtaining funds from the grant payment system, the recipient acknowledges acceptance of the terms and conditions of the award and is obligated to perform in accordance with the requirements of the award. 45 C.F.R. pt. 74 et seq. (2011).

136. By drawing funds, the federal grant Awardee certifies that proper financial management controls and accounting systems to include personnel policies and procedures have been established to adequately administer Federal awards and funds drawn down are being used in accordance with applicable federal cost principles, regulations and the President's Budget and Congressional Intent.

137. As part of the Subaward Agreement, CARD stated that there were no conflicts of interest or "Significant Financial Interests" that prevented the receipt of federal grant monies from the Prime Award.

138. Mount Sinai and CARD clinicians have long-standing personal and professional relationships and shared financial motives.

139. Both institutions profit from the study and treatment of asbestos related disease.

140. Dr. Black serves as an adjunct professor at Mount Sinai School of Medicine.

141. Dr. Black and Mt. Sinai doctors have co-authored studies on asbestos related issues in the past.

142. CARD has periodically employed physicians at CARD sent by Mount Sinai.

143. The program director and principal investigator involved in the Mount Sinai Prime Award was a B Reader physician to whom CARD paid thousands of dollars annually to perform B Reads of CARD patient's chest X-rays.

144. According to Mount Sinai grant sub award documents, Dr. Black and other CARD staff members were paid a total of $137,112 in salary from Mt. Sinai sub award funds.

145. The sub award also awarded CARD $106,808 for "Patient Care Costs."

146. That sub-award issued CARD $5,500 for "CT scans only at CARD." (Sub Award No. 0254-5674-4609).

147. CARD has not ever had a CT scanner at its facility.

148. By applying for and accepting these funds, CARD certified that it had no conflicts of interest, that the funds were medically necessary and would be used in accordance with federal rules and regulations governing federal grants stated herein.

149. Each false and misleading statement referenced herein made by CARD in support of payment of federal grant sub-award funds constitutes a false claim for payment by the federal government pursuant to 31 U.S.C. § 3729 as set forth below.

False Claims for Medicare Payments

150. In hundreds of cases, CARD knowingly submitted patients for Medicare coverage based on the unsupported, false and misleading "diagnosis" of "Asbestosis" or "Pleural thickening Pleural plaques" recorded on EHH forms.

151. After "diagnosing" patients with an asbestos related disease, CARD certified that diagnosis on EHH forms and other documents and forwarded same to the federal government representing that these individual patients carried a Medicare qualifying diagnosis of asbestos related disease.

152. In some cases, CARD and Dr. Black appear to have certified patients for Medicare coverage on EHH forms when no outside X-rays or CT scans were obtained.

153. In hundreds of other cases, CARD and Dr. Black certified patients for Medicare when outside B readers and Radiologists found no signs of Asbestosis or Pleural thickening/Pleural plaques on chest x-rays and/or chest CT scans.

154. In a significant percentage of these cases, CARD and Dr. Black certified patients for Medicare, despite the fact that CARD's own panel of Peer Review Radiologists found no signs of Asbestosis or Pleural thickening/Pleural plaques on CT scans.

155. Since 2011, and continuing until the present, as a result of CARD's false certifications of an ARD diagnosis, hundreds of CARD patients have received and continue to receive Medicare benefits even though they do not in truth and fact have "Asbestosis" and/or "Pleural thickening or Pleural plaques."

156. Once enrolled in Medicare, these patients have received ongoing treatment at CARD and elsewhere that was billed to Medicare directly.

157. CARD has prescribed medications, oxygen therapy, home assistance and other treatments and services paid for by federal funds based on a false diagnosis of asbestos related disease.

158. Based on this false diagnosis, CARD continued to treat these patients and to submit, or cause to be submitted, bills to Medicare for medically unnecessary medications, treatments and services.

159. Each statement referenced herein, made, caused to be made, or forwarded by CARD in support of payment of Medicare funds for medical treatment, medications and services constitutes a false claim for payment by the federal government pursuant to 31 U.S.C. § 3729 as set forth below.

False Claims for Social Security Disability and Pilot Program Benefits

160. CARD has also assisted patients in obtaining Social Security Disability benefits and Pilot Program benefits based on the unsupported, false and misleading "diagnosis" of "Asbestosis" or "Pleural thickening Pleural plaques" recorded on EHH forms.

161. After "diagnosing" patients with an asbestos related disease, CARD assisted patients in making claims for Social Security Disability benefits by providing, completing and/or transmitting Form SSA-827 and other forms to the federal government with information certifying that the individual patient carried a qualifying diagnosis of asbestos related disease.

162. CARD has likewise assisted CARD patients in obtaining Pilot Program benefits for services such as housekeeping, lawn maintenance and other forms of assistance.

163. In many cases, CARD faxed, mailed or otherwise transmitted these forms to the federal government on the patient's behalf within days of rendering an unsupported diagnosis of ARD.

164. As a result of CARD's false certifications, hundreds of CARD patients have received and continue to receive Social Security Disability Insurance and Pilot Program benefits even though they do not in truth and fact have "Asbestosis" and/or "Pleural thickening or Pleural plaques."

165. Each statement referenced herein, made or forwarded by CARD in support of payment of federal funds for Social Security Disability Benefits, the Pilot Program, the Federal Libby Asbestos Specialty Healthcare plan (FLASH) or payment of other federal funds related to disability benefits based on the diagnosis and treatment of Asbestos Related disease pursuant to the Affordable Care Act at 42 U.S.C. § 1881A constitutes a false claim for payment by the federal government pursuant to 31 U.S.C. § 3729 as set forth below.

False Claims for Medically Unnecessary Prescriptions of Opioid and Narcotic Pain Medication

166. Data from the United States Drug Enforcement Agency shows that more than 245 million prescription pain pills were supplied to Montana from 2006 to 2012.

167. According to this data, the bulk of these legally prescribed opioids in Montana was mostly confined to the northwest corridor of the state. *See* Daily Interlake: *"Data Shows Unusually High Distribution of Painkillers in Northwest Montana at Height of Crisis."* (August 12, 2019).

168. Lincoln County, home to the CARD clinic, showed the highest number of total pain pills per person for the entire State of Montana during that seven-year period. *Id.*

169. Data from the Centers for Disease Control shows that Lincoln County continued to experience the highest rates for opioid prescriptions dispensed per 100 residents from 2009 to 2016. *Id.*

170. CARD, from its inception in 2003 to the present, through Dr. Black and others, has prescribed narcotic and opioid pain medications to lung-screening patients to treat "pleuritic chest pain" and other conditions supposedly related to asbestos related disease.

171. These prescription pain medications include scheduled opioid drugs and narcotic painkillers including Oxycodone, Hydrocodone, OxyContin, Vicodin, Lortab, Percocet, Tramadol, Codeine, Morphine, Fentanyl and other controlled substances.

172. In many cases, CARD's prescriptions for pain medications were not medically necessary, as patients receiving scripts did not carry a legitimate diagnosis of asbestos related disease as defined by the American Thoracic Society, the standards of care for diagnosis and treatment of ARD, Medicare provisions found at 42 U.S.C. § 1881A, and CARD's own federal funding requirements.

173. CARD knowingly prescribed pain medications in many individual cases despite CARD's knowledge that these patients lacked a federally recognized basis for an ARD diagnosis in that these patients lacked positive signs of disease on CT scan or B read according to Outside Radiologists.

174. As a consequence of CARD's misdiagnosis of ARD and over-prescription of pain medication, CARD patients have abused opioids in and around Libby, Montana and elsewhere.

175. In some of these cases, CARD continued to renew prescriptions for pain medication even when CARD's own records noted that patients were exhibiting drug-seeking behavior, were receiving "double scripts" to obtain pain medications and did not appear to show any signs of malignant asbestos related disease.

176. In many of the aforementioned cases, these patients' prescription pain medications were paid for by Medicare or some other form of government funding.

177. CARD's statements certifying a false ARD diagnosis on EHH forms and other patient medical records, as well as CARD's scripts, prescriptions and orders for drugs that were medically unnecessary based on this false diagnosis, sent to Medicare either directly or through other medical care providers, constitute false statements in support of claims for payment of government funds.

The Apparent Correlation between Prescription Pain Medication and Disability Status in Libby, Montana

178. Many of CARD's patients receiving opioid pain medication are on disability status due to CARD's diagnosis of asbestos related disease.

179. CARD has assisted hundreds of patients to obtain Social Security Disability Insurance benefits as a result of CARD's diagnosis of asbestos related disease.

180. Lincoln County has one of the highest rates of disabled residents of any counties in Montana.

181. According to U.S. Census data compiled by the University of Montana, Lincoln County – where asbestos disease linked to the W.R. Grace vermiculite mine is still prevalent – was one of six counties in Montana to have a disability rate between 19 and 36.9 percent from 2012 to 2017. *See* Kianna Garner, *Data Shows Unusually High Distribution of Painkillers in Northwest Montana at Height of Crisis*, Daily Interlake (Aug. 12, 2019) https://www.dailyinterlake.com/local_news/20190812/data_shows_unusually_high_distribution_of_painkillers_in_nw_montana_at_height_of_crisis.

182. According to figures published by the United States Census Bureau, the average disability rate for Montana from 2013 to 2017 was 9.4%. *See* https://www.census.gov/quickfacts/fact/table/MT/DIS010217#DIS010217.

183. Rising disability rates are associated with increased rates of chronic pain diagnosis. *Id.*

184. Through the aforementioned acts and omissions, hundreds of CARD patients through the years have been traumatized both by CARD's false diagnosis of asbestos related disease, and news that they should consider themselves permanently disabled.

185. CARD's acts and omissions enumerated above not only harmed the United States, but also caused further harm to an already vulnerable population of people in Libby, Montana.

FALSE CLAIMS ACT COUNTS I-III

186. BNSF incorporates and re-alleges all of the foregoing allegations herein.

187. Since 2011, and continuing until the present, based on the facts alleged above, each CARD script for prescription pain medication; each false statement made by CARD to induce the federal government to continue funding CARD's federal grants; each CARD bill, claim, application, statement or invoice for grant money or payment by the federal government for unused, ignored or medically unnecessary B-reads, CT scans, radiographic interpretations or other medically unnecessary treatments; each CARD statement to secure Mt. Sinai sub award funds to pay for CT scans taken *at* CARD; each CARD script, diagnostic record, EHH

form or any other statement made by CARD, or caused to be made by CARD, and made in support of claims for payment by the federal government based on a false diagnosis of ARD, and submitted directly or indirectly to Medicare, the Centers for Disease Control, the ATSDR, the Pilot Program, the Social Security Administration or any other government agent or contractor; and any other unauthorized claims, false statements, half-truths and acts of concealment referenced above constitute False Claims for payment by the federal government pursuant to 31 U.S.C. § 3729, as set forth below.

COUNT I

False Claims Act Violations
31 U.S.C. § 3729(a)(1)(A)

188. BNSF incorporates and re-alleges all of the foregoing allegations herein.

189. Based upon the acts described above, CARD knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the federal government.

190. CARD knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government.

191. The terms "knowing" and "knowingly" mean that a person with respect to information has actual knowledge of the information; acts in deliberate ignorance

of the truth or falsity of the information; or acts in reckless disregard of the truth or falsity of the information.

192. The United States, unaware of the falsity of these claims, records, and statements made by the Defendant, and in reliance on the accuracy thereof, paid money to the Defendant and/or other individuals for the fraudulent claims.

193. The United States and the general public have been damaged as a result of CARD's violations of the False Claims Act.

COUNT II
False Claims Act Violations
31 U.S.C. § 3729(a)(1)(B)

194. BNSF incorporates and re-alleges all of the foregoing allegations herein.

195. Based upon the acts described above, CARD knowingly made, used, or caused to be made or used, a false record or statement material to a false or fraudulent claim.

196. The United States, unaware of the falsity of these claims, records, and statements made by the Defendant, and in reliance on the accuracy thereof, paid money to the Defendant and/or other individuals for the fraudulent claims.

197. The United States and the general public have been damaged as a result of CARD's violations of the False Claims Act.

COUNT III
False Claims Act Violations
31 U.S.C. § 3729(a)(1)(G)

198. BNSF incorporates and re-alleges all of the foregoing allegations herein.

199. CARD knowingly made, used, or caused to be made or used, false records or statements material to an obligation to pay or transmit money or property to the government, or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the government.

200. The United States, unaware of the falsity of these claims, records, and statements made by the Defendant, and in reliance on the accuracy thereof, paid money to the Defendant and/or other individuals for the fraudulent claims.

201. The United States and the general public have been damaged as a result of CARD's violations of the False Claims Act.

202. By virtue of the false records or false statements knowingly made, used or caused to be made or used, CARD is liable to the United States government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990, plus 3 times the amount of damages which the government sustains because of the acts of Defendant.

PRAYER FOR RELIEF

1. For the reasons set forth above, BNSF, on behalf of the United States, respectfully requests this Court to find that CARD has damaged the United States government as a result of its conduct under the False Claims Act. BNSF prays that judgment be entered against Defendant for all applicable damages, including but not limited to the following:

a. Actual damages in an amount equal to the costs paid by the government as a result of CARD's False Claims.

b. Civil Penalties in an amount of three times the actual damages suffered by the government.

c. Imposition of monetary penalties, including penalties up to $10,0000 for each individual false claim violation, as allowed under the False Claims Act. 31 U.S.C. § 3729 et seq.

d. BNSF seeks a fair and reasonable amount of any award for its contribution to the government's investigation and recovery pursuant to 31 U.S.C. §§ 3730(b) and (d) of the False Claims Act.

e. Attorney's fees and costs awarded to BNSF.

f. Pre-judgment and post judgment interest.

g. All other relief on behalf of the BNSF and/or United States government to which they may be entitled at law or equity.

DATED this 18th day of February, 2021.

KNIGHT NICASTRO MACKAY, LLC

By: */s/ W. Adam Duerk*
W. Adam Duerk
Attorneys for Realtor BNSF Railway Company

CERTIFICATE OF SERVICE

I, the undersigned, an employee of the law firm of Knight Nicastro MacKay, LLC hereby certify that I served a true and complete copy of the foregoing on the following persons by the following means:

1, 2 CM/ECF
_____ Hand Delivery
_____ Mail
_____ Overnight Delivery Service
_____ Fax
_____ E-Mail

1. Clerk, U.S. District Court

2. Michael Kakuk
   Assistant U.S. Attorney
   U.S. Attorney's Office
   P.O. Box 8329
   105 E. Pine, 2nd Floor
   Missoula, MT 59802
   Michael.kakuk@usdoj.gov

By: */s/ W. Adam Duerk*
W. Adam Duerk